

REMARKS/ARGUMENTS

In response to the rejection of claims 23 and 33 under 35 U.S.C. §101, applicant respectfully submits that claims 23 and 33 have been amended to overcome the rejection in accordance with the Examiner's suggestion.

Claims 22-25, 27, 28, 32-35, 37 and 38 are rejected under 35 U.S.C. §102(b) as being anticipated by or in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,077,236 issued to Cunningham. Specifically, regarding claims 22 and 25 the examiner states:

Regarding claim 22, Cunningham discloses a cardiac motion sensor unit comprising an acceleration sensing device 2 that generates a signal representative of movement of a cardiac wall, a conductor device 2 that generates a signal representative of movement of a cardiac wall, a conductor device with an elongated insulator body (insulated wires 7 and 8 as discussed in col. 6 lines 47-50) that transmit the signal to an electronic device, and a connector device (generally shown by the switching arrangement with positions 13 and 113 as shown in Fig. 15). The examiner also notes that, while not explicitly shown, the pacing/sensing lead must have some form of traditional connector device (commonly a connector pin arrangement) if it is to connect to the electronic device 9. In any event, the switching arrangement is considered to constitute a connector device.

Regarding the term "molded into," the examiner considers such a term to be related to a product-by-process limitation. Such claims are only limited by the structure implied by the steps, and not the step(s) itself. The claimed product appears to be the same or similar to that of the Cunningham device since both products would contain an insulating layer over the conductor. Furthermore, it would not appear to make any difference as to how the insulative material was applied from an operational standpoint. Clearly an insulator body is required to prevent signal interference and shortening of signals between conductors. How such a body is constructed with respect to a conductor is of little consequence to this issue. A related comment applies to claim 25.

Applicant respectfully traverses the Examiner's rejection and submits that claims 22 and 25 are not anticipated by Cunningham. While Applicant admits that both the present invention and Cunningham are devices that sense cardiac contractions, Cunningham does not teach or disclose structure corresponding to the recitation in claim 22 of a conductor molded into an elongated insulator body that transmits the signal representative of

movement of a cardiac wall from the acceleration sensing device. Cunningham also fails to disclose a connector device configured for removable attachment of the motion sensor unit to the electronic device.

The Examiner represents that Cunningham discloses "a conductor device with an elongated insulator body (insulated wires 7 and 8 as discussed in col. 6 lines 47-50) that transmit the signal to an electronic device." Applicant respectfully submits that this assertion does not set forth the elements of the conductor device claimed in claim 22. Moreover, nowhere is there any mention in Cunningham of an elongated insulator body or that a conductor device is molded into an elongated insulator body. Upon referring to the drawings and specification of Cunningham at lines 22-24 Column 4 it is clear that the conductor device disclosed in Cunningham is nothing more than "a two-wire conductor of simple form." The specification also points to Figure 2 and states that " 7 and 8 indicate the electrically insulated wires which run inside the catheter and connect the components of the device in question." Because the specification clearly states that wires 7 and 8 "run inside the catheter," they cannot be molded into an elongated insulator body. Further, Applicant also respectfully submits that the specification of Cunningham clearly indicates that there is no elongated insulator body. Applicant admits that Cunningham does disclose a catheter as part of its invention. However, the catheter is not the same as or similar to the elongated insulator body of the present invention. To the extent there is an attempt by the Examiner to equate the catheter disclosed in Cunningham to an element disclosed in the present invention, Applicant respectfully submits that the present invention also includes leads. Referring the Examiner to Figure 3 and page 7 lines 4-8 of the specification of the present invention, it specifically states:

The implantable lead 26 comprises a cylindrical lead 34 with a conductor used for sensing cardiac electrical activity and delivering stimulation to the cardiac wall. The cylindrical lead 34 is concentrically encompassed by a second cylindrical lead 30 possessing a similar conductor, and the cylindrical lead 34 has an inner lumen 28.

It is the leads of the present invention which function in the capacity as the housing that has the acceleration sensor positioned in its tip. The acceleration sensor of the present invention "comprises a cardiac motion sensor 42 and a connector coupled together by an elongate body 41. The elongate body 41 comprises two electrical conductors 43, 47 encompassed by an insulator 49 extending longitudinally. The electrical conductors 43, 47 electrically connect the cardiac motion sensor 42 located at the distal end of the acceleration sensor unit 44 with the connector 45 located at the proximal end of the acceleration unit 44." Accordingly, in addition to the lead of the present invention, the acceleration sensor unit includes an elongated body into which the conductor is molded.

By having the conductor of the acceleration sensor unit molded into the elongated insulator body that serves as a link between the acceleration sensor and the connector, "should it be necessary, the acceleration sensor unit 46 may be removed from the lead 26 while the lead 26 remains installed in the heart 100." See Application No. 10/004,686 specification at page 8 lines 7-8. Accordingly, it is the structure of the acceleration unit and the manner in which the conductor is molded into the elongated insulator body that gives the acceleration sensor unit its ability to be removed from within the lead.

Cunningham discloses a catheter and wires 7 and 8 disposed in the inner lumen of the catheter. While a catheter having wires running through its inner lumen may appear similar to the present invention, the wires 7 and 8 to which the Examiner directs the Applicant are not embedded into the wall assembly of an elongated body connected between the acceleration sensor and a connector. Claim 22 specifically claims that a conductor is molded into an elongated insulator body. Cunningham does not disclose any structure corresponding to this limitation.

Cunningham also fails to disclose a connector of any kind. Applicant would agree that wires 7 and 8 have to be connected to the electronic device. However, there is no discussion of an actual connector. The connector of the present invention is one that allows the acceleration sensor unit to be removed from the device without removing the lead. Claims 22 and 32 have been amended to include this limitation. There is no such connector disclosed in Cunningham. In addition, Applicant respectfully submits that the

internal circuitry of Cunningham teaches away from a connector of the type disclosed in the present invention. The present invention discloses an acceleration sensor unit comprised of a conductor molded into an elongated insulator body that serves as a link between the acceleration sensor and a connector, wherein the acceleration sensor unit may be disposed in the inner lumen of a lead and connected to a implantable device. The acceleration sensor may also be removed from the lead without disrupting the sensing, pacing and defibrillation functions provided by the lead and implantable device. There is a separate and removable electrical conductive path for the motion detection function, which does not interfere with the sensing, pacing and defibrillation functions. In contrast, Cunningham does not have separate conductive paths. Cunningham discloses that the link from the transducer and its associated electronic circuit to the master control unit is a two-wire link that permits alternation between the phases of sampling of the accelerometer and those of sensing, pacing and defibrillation. See Column 4 lines 56-60 of Cunningham. It is also stated at Column 4 lines 34-40 of Cunningham:

Assuming that 7 is the positive reference electrode supplying the transducers and the corresponding timing circuit 10, the subcutaneous unit 9 changes from the PACING/SENSING state indicated by 113 to the SENSORS state indicated by 13, for the measurement of the modulus or of the mean of the NHA values read from the three transducers within the cardiac cycle in question.

Accordingly, Applicant respectfully submits that the structure of Cunningham teaches away from a connector of the type disclosed and claimed, in view of the amendment to claims 22 and 32, in the present application. Indeed, the Examiner indicates that there is no discussion of a connector. In view of the above amendments to claims 22 and 32 and the above remarks, Applicant respectfully submits that claims 22 and 32 are in condition for allowance. Applicant further submits that claims 23-31 and claims 33-40 are in condition for allowance by virtue of their dependency on claims 22 and 32. Accordingly, Applicant respectfully request reconsideration of the rejections and objections to the claims.

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CONCLUSION

Should the Examiner have any questions or comments, please contact the undersigned at 404-954-5100.

Respectfully submitted,

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